UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/497,943	02/04/00	BEHLKE M	7614-018-999

HM12/0718
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EXAMINER	
SISSON,B	
ART UNIT	PAPER NUMBER
1655	15

DATE MAILED: 07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/497,943	Applicant(s) BEHLKE ET AL.	
	Examiner Bradley L. Sisson	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-38 40-54* is/are rejected.

7)☒ Claim(s) *39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 29-54, in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 41 and 49-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 41 is indefinite as it lacks antecedent support for "the Signal Domain."

5. Claims 49, 50 depend from canceled claim 1; and claim 51 depends from canceled claim 15. Claims 52-54, which depend from said claim 51, are similarly rejected as they fail to overcome this issue of indefiniteness. Accordingly, claims 49-554 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 29, 30, 32, 33, 40, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Shuber.

Shuber, column 2, third paragraph, and column 4, third paragraph, discloses the use of a chimeric primer that is described as being configured 5'-XY-3'. The "X" domain "comprises a sequence that dos not hybridize to the target sequence." The "Y" domain "comprises a sequence contained within or flanking the target sequence or its complement." Accordingly, the "X" domain meets the limitations of applicants "Signal Template Domain" and the "Y" domain meets the limitations of the "Substrate hybridization Domain" of the "first sequence." The target sequence meets the limitations of applicant's second sequence. As seen at column 4, the respective domains may be comprised of nearly any nucleotide sequence and that it can range in length from 17 to 25 bases. Such a limitation is considered to meet the limitation of claim 34 where the Substrate Hybridization Domain "comprises a sequence of about 5 to 10 nucleotides" (emphasis added).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shuber in view of Khan et al

10. See above for the basis of the rejection as it relates to the teachings of Shuber.

11. Khan et al., column 8, disclose that suitable templates include DNA as well as RNA.

12. It would have been obvious to one of ordinary skill in the art to have modified the method of Shuber whereby RNA was used as a template and to have used a RNA dependent DNA polymerase so as to generate cDNA runoffs as such would be more resistant to degradation and thereby provide the artisan with a more stable resource for further investigation.

13. In view of the well-developed nature of the art, the skilled artisan would have had a reasonable expectation of success.

14. Claims 35-38, 41-43 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shuber in view of Grossman et al. and Khan et al.

See above for the basis of the rejection as it relates to the disclosure of Shuber.

Shuber does not disclose the use of homopolymeric tails.

Grossman et al., column 19, discloses the generation of homopolymeric tails. Also disclosed is the use of a detectable nucleotide, e.g., a fluorophore (applicant's fluorescein).

Khan et al., column 5, sixth paragraph, disclose a plethora of labels that can be used in primer extension reactions. As seen therein, such labels include fluorophores, radioisotopes, biotin, etc.

Khan et al., column 5, disclose the use of modified nucleotides, e.g., dideoxynucleotides, that proscribe primer elongation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated any one of the labels disclosed by Khan et al., and Grossman et al., into either strand, or the nucleotides to be incorporated into the prime extension product of Shuber as such would have accorded the ordinary artisan with a easy means for identifying the product of any reaction as well as individual reagents.

It would have also been obvious to have incorporated the use of a chain terminating nucleotide into a specific sequence so to limit the amount and direction of any extension reaction. Given the well developed use of chain terminating nucleotides, the ordinary skilled artisan would have had a reasonable expectation of success.

15. Claim 45-47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shuber in view of Brown.

See above for the basis of the rejection as it relates to the disclosure of Shuber.

Shuber does not disclose the use of 2, 6-diaminopurine.

Brown et al., discloses the use of 2, 6-diaminopurine in oligonucleotides and their use in primer extension reactions.

It would have been obvious to one of ordinary skill in the art to have incorporated the use of 2, 6-diaminopurine into the sequences utilized by Shuber for the obvious improvements as disclosed by Brown.

Allowable Subject Matter

16. Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephanie Zitomer can be reached on (703) 308-3985. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1655

BLS
July 15, 2001